

### **Remarks**

For the reasons provided below, Applicants disagree with, and traverse, the rejection of currently pending claims 21-32.

#### ***Rejection under 35 U.S.C. § 101***

Claims 21-32 were rejected as allegedly "drawn to an invention with no apparent or disclosed specific and substantial credible utility." *See*, Paper No. 9, page 2, last full sentence. More particularly, it was alleged that "The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder [or] physiological process which one would wish to manipulate for a desired clinical effect." *See*, Paper No. 9, page 3, first full sentence.

Applicants respectfully disagree and traverse. The present specification has described the full-length polypeptide of the invention as a 7-transmembrane G-protein coupled amine (*i.e.*, neurotransmitter) receptor. *See e.g.*, specification at: page 1, first paragraph; page 3, first paragraph; and, page 4, third paragraph. Furthermore, the specification has described neurotransmitter receptors as "implicated in numerous pathophysiologies and treatments including, movement disorders, schizophrenia, drug addiction, anxiety, migraine headaches, epilepsy, myoclonus, spastic paralysis, muscle spasm, schizophrenia, cognitive impairment, depression, Parkinson's Disease and Alzheimer's Disease..." *See e.g.*, specification at page 4, first paragraph. Therefore in view of such disclosure, Applicants submit that the instant application has disclosed particular diseases, disorders, and physiological processes one would wish to manipulate for a desired clinical effect.

In the pending Office Action, it was also alleged that:

The instant claims are drawn to a protein of as yet undetermined function or biological significance. Until some actual and specific significance can be attributed to the protein identified in the specification as a human amine receptor, or the gene encoding it, the instant invention is incomplete...Since the instant specification does not disclose a credible "real world" use for the disclosed receptor protein then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

*See*, Paper No. 9, page 4, second paragraph.

Applicants respectfully disagree and traverse. Applicants submit for consideration PCT Publication WO 03/001882 A2 as further evidence that the present application describes a 7-transmembrane G-protein coupled amine (*i.e.*, neurotransmitter) receptor.<sup>1</sup> WO 03/001882 A2 also supports the present specification's implication of this receptor in schizophrenia. *See*, specification page 4, first paragraph. In particular, Applicants note that WO 03/001882 A2 discloses that transgenic mice with disruptive mutations of the receptor exhibit a behavioral deficit characteristic of human schizophrenia (*i.e.*, a deficit in prepulse inhibition of the startle reflex). *See e.g.*, WO 03/001882 A2: page 17, lines 17-21 and, page 49, line 3 to page 50, line 34. Therefore, Applicants submit that WO 03/001882 A2 further supports "some actual and specific significance" and a "credible 'real world' use" of the presently claimed receptor as described in the specification as originally filed.

In view of the explanations and supporting document provided above Applicants submit that the presently claimed invention has utility sufficient for the requirements of 35 U.S.C. § 101. Therefore, Applicants respectfully request the rejection of claims 21-32 under 35 U.S.C. § 101 be reconsidered and withdrawn.

***Rejection under 35 U.S.C. § 112, First Paragraph***

Claims 21-32 were also rejected under 35 U.S.C. § 112, first paragraph, for the reasons alleged in the rejection under 35 U.S.C. § 101. *See*, Paper No. 9, page 5, first full paragraph. However, in view of the explanations and supporting document provided above with regard to the rejection under 35 U.S.C. § 101, Applicants submit that the rejection under 35 U.S.C. § 112 on this basis has also been overcome.

Claims 21, 25-30, and 32 were rejected under 35 U.S.C. § 112, first paragraph, based on the deposited material recited therein. *See*, Paper No. 9, page 5, item 4. In particular, an averment pertaining to the deposited material has been requested. *See*, Paper No. 9, page 6, first full paragraph. Accordingly, Applicants submit the following statement regarding the deposited material:

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<sup>1</sup> The PNR receptor described in PCT WO 03/001882 A2 and the receptor described in the present application are identical.

### **Availability of the Deposit**

Human Genome Sciences, Inc., the assignee of the present application, has deposited biological material under the terms of the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure with the following International Depository Authority: American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, Virginia 20110-2209 (present address). The deposit was made on June 1, 1995, accepted by the ATCC, and given ATCC Accession Number 97181. In accordance with M.P.E.P. § 2410.01 and 37 C.F.R. § 1.808, assurance is hereby given that all restrictions on the availability to the public of ATCC Accession Number 97181 will be irrevocably removed upon the grant of a patent based on the instant application, except as permitted under 37 C.F.R. § 1.808(b). A partially redacted copy of the ATCC Deposit Receipt for Accession Number 97181 is enclosed herewith.

Additionally, the Examiner has requested that "the deposit must be referred to in the body of the specification and be identified by deposit (accession number) number, name and address of the depository, and the complete taxonomic description." *See*, Paper No. 9, page 6, second paragraph. Applicants note that the Preliminary Amendment submitted on November 20, 2001 included an amendment of page 7, second paragraph (starting at line 10) to include the deposit number as well as the name and address of the depository. With regard to the request for a "complete taxonomic description", Applicants note that the deposited material is a DNA plasmid containing a cDNA encoding the presently claimed receptor polypeptide. Accordingly, Applicants have herein included a second amendment to the second paragraph on page 7 to replace the phrase "of the clone" with "in the plasmid". Applicants also note that the Preliminary Amendment submitted on November 20, 2001 included an amendment to page 39, first paragraph (starting at line 1) to replace "ATCC # \_\_\_\_\_" with "ATCC No. 97181" in Example 2. Similarly, Applicants herein submit a similar amendments for Examples 1 and 3 to replace "ATCC # \_\_\_\_\_" with "ATCC No. 97181" on page 37 and page 42.

In view of the above statement and amendments, Applicants submit that the rejection of claims 21, 25-30, and 32 under 35 U.S.C. § 112, first paragraph, based on the deposited material recited therein has been accommodated. Therefore, Applicants respectfully request that this rejection be withdrawn.

### ***Rejection Under 35 U.S.C. § 102***

The Examiner has denied the present application's benefit claims under 35 U.S.C. § 120 based on the above cited rejections under 35 U.S.C. § 112, first paragraph. And, the Examiner then rejected claims 21 to 32 under 35 U.S.C. § 102(b) as allegedly anticipated by Zeng *et al.*, published Jan. 26, 1998. *See*, Paper No. 9, page 7, first paragraph.

Applicants respectfully disagree and traverse the denial of the application's benefit claims under 35 U.S.C. § 120 and the rejection of claims 21-32 under 35 U.S.C. § 102(b) based on the rejections under 35 U.S.C. § 112, first paragraph. In view of the amendments, explanations, and evidence provided herein and herewith, Applicants submit that the rejections under 35 U.S.C. § 112, first paragraph, have been accommodated or overcome. Moreover, since the present application contains the same written description, and includes no new matter, as application number 08/467,559 (filed June 6, 1995) to which the present application claims benefit, the publication by Zeng *et al.* (Jan. 26, 1998) does not constitute prior art against the present application. Therefore, Applicants respectfully request withdrawal of the denial the present application's benefit of priority claims under 35 U.S.C. § 120 and withdrawal of the rejection of claims 21-32 under 35 U.S.C. § 102(b).

Applicants respectfully request that the above-made amendments, remarks, and documents be entered and made of record in the file history of the instant application.

### **Conclusion**

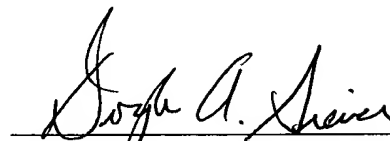
In view of the foregoing submitted amendments, remarks and evidentiary documents, Applicants believe that this application is in condition for allowance. An early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite allowance of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of

time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

Dated: Jan 12, 2004



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MJH/DAS/mr



# American Type Culture Collection

12301 Parklawn Drive • Rockville, MD 20852 USA • Telephone: (301)231-5520 Telex: 898-055 ATCCNORTH • FAX: 301-770-2587

## BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

### INTERNATIONAL FORM

#### RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

**To: (Name and Address of Depositor or Attorney)**

Human Genome Sciences, Inc.  
Attention: Robert H. Benson  
9410 Key West Avenue  
Rockville, MD 20850

Deposited on Behalf of: Human Genome Sciences, Inc.

**Identification Reference by Depositor:**

DNA Plasmid, 563237 (HGS Docket PF188)

**ATCC Designation**

97181

The deposits were accompanied by: ☐ a scientific description ☐ a proposed taxonomic description indicated above.

The deposits were received June 1, 1995 by this International Depository Authority and have been accepted.

**AT YOUR REQUEST:**

☒ We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years after the date of deposit, and for a period of at least five years after the most recent request for a sample. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested June 8, 1995. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

Date: June 14, 1995

Annette L. Bade, Director, Patent Depository

cc: Greg D. Ferraro